

REMARKS

Applicant thanks the Examiner for the thorough consideration given the present application. Claims 6, 8 and 9 are cancelled herein without prejudice to or disclaimer of the subject matter set forth therein. Claims 1-5 and 7 are pending. Claims 1, 2, 5 and 7 are amended. Claims 1, 2 and 7 are independent. The Examiner is respectfully requested to reconsider the rejections in view of the amendments and remarks set forth herein.

Examiner Interview

If, during further examination of the present application, a discussion with Applicants' Representative would advance the prosecution of the present application, the Examiner is encouraged to contact Carl T. Thomsen (Registration No. 50,786) at 1-703-208-4030 (direct line) at his convenience.

Claim for Priority

The Examiner has not acknowledged Applicant's claim for foreign priority based on ZA 03/5160 filed on July 2, 2003. Clarification is requested in the next official communication.

Information Disclosure Citation

Applicant thanks the Examiner for considering the reference supplied with the Information Disclosure Statement filed May 10, 2007, and for providing Applicant with an initialed copy of the PTO form filed therewith.

Rejection Under 35 U.S.C. § 112, second paragraph

Claims 6 and 7 stand rejected under 35 U.S.C. § 112, second paragraph. This rejection is respectfully traversed.

The Examiner has set forth certain instances wherein the claim language is not clearly understood.

In order to overcome this rejection, Applicant has amended claim 6-7 to correct each of the deficiencies specifically pointed out by the Examiner. Applicant respectfully submits that the claims, as amended, particularly point out and distinctly claim the subject matter which Applicant regards as the invention. Accordingly, reconsideration and withdrawal of this rejection are respectfully requested.

Rejections Under 35 U.S.C. § 102(b)

Claims 1, 2 and 5 stand rejected under 35 U.S.C. § 102(b) as being anticipated by Van Cleave (U.S. Patent 4,037,937);

Claims 2-9 stand rejected under 35 U.S.C. § 102(b) as being anticipated by Saleh et al. (U.S. Patent 6,387,382);

Claims 2 and 4 stand rejected under 35 U.S.C. § 102(b) as being anticipated by Merat et al. (EP 056748); and

Claim 2 stands rejected under 35 U.S.C. § 102(b) as being anticipated by Bettel et al. (WO98/29085).

These rejections are respectfully traversed.

Amendments to Independent Claims 1, 2 and 7

While not conceding the appropriateness of the Examiner's rejection, but merely to advance prosecution of the present application, each of independent claims 1, 2 and 7 has been amended to recite a combination of features, including *inter alia*

“the antimicrobial agent consisting of an essential oil selected from a group consisting of the essential oils of *Melaleuca alternifolia*, *Melaleuca dissitiflora*, and *Melaleuca linariiflora*,

wherein the composition consists of no more than the water repellent agent and the antimicrobial agent”.

As the Examiner points out on page 3 of the Office Action, Tea Tree Oil, as disclosed in claims 6 and 7 as originally filed, may be extracted from any of *Melaleuca alternifolia*, *Melaleuca dissitiflora*, and *Melaleuca linariiflora*.

The present invention is not anticipated by any of the cited references for at least the following reasons:

Regarding Van Cleave

Van Cleave provides a treatment directed at preventing the phenomenon of capillary action and surface tension which arises within the ear canal. The primary purpose of the Van Cleave treatment is to reduce surface tension in the water retained in the ear canal, thereby to allow the water to run out normally when the person's head is tilted (column 4; lines 10 to

17). This is why Van Cleave proposes the use of an aqueous surface tension reducing agent into the ear (column 2; lines 6 to 11).

In its entirety, the Van Cleave patent teaches the use of surface tension reducing agents, surface active agents or surfactants, the primary purpose of which is to reduce the capillary adhesion of water retained in the outer ear canal to the skin of the canal. The document goes on to list a large number of such surface active agents.

Against this, the present patent application proposes the use of an inert oil (in the form of silicone oil in the preferred form of the invention) simply to line the ear canal with a thin film of oil prior to swimming, the intention being simply to prevent water contact during and after swimming, even if the water is retained within the ear after swimming.

This is a greatly simplified approach, the advantage of which lies in a lower constituent cost and a greatly reduced manufacturing cost.

In support of the rejection based on Van Cleave, the Examiner relies on references drawn from several different places within the patent document, rather than from a clear, coherent description of the invention found in one place in the document, almost creating a mosaic of references.

It is our understanding that rejections under 35 U.S.C. § 102(b) require a clear statement, describing the invention. It is submitted that the Van Cleave reference does not contain such a clear statement or description of the invention in its entirety.

Further, Van Cleave makes no mention of “the antimicrobial agent consisting of an essential oil selected from a group consisting of the essential oils of *Melaleuca alternifolia*,

Melaleuca dissitiflora, and *Melaleuca linariiflora*”, as set forth in independent claims 1, 2 and 7 of the present invention.

For this reason, Applicant submits that the Van Cleave patent does not describe the present invention, as set forth in each of independent claims 1, 2 and 7, in a manner sufficient to anticipate these inventions.

Regarding Saleh et al.

Saleh et al. relates to an oil-in-water emulsion (column 1; lines 5 to 10). The multipurpose skin preparation of Saleh is an example of silicone-based skin preparations, of which there are many. Throughout the document, reference is made to the fact that the skin preparation is an emulsion that contains a large number of constituents in both its oil and aqueous phases.

The Saleh et al. composition is very different from the very simple film forming oil-in-oil formulation described and claimed in the present patent application.

Once again, the Examiner relies on references located throughout the document to find anticipation. In addition, the examiner relies on the assumption that a liquid formulation is “inherently capable of being instilled in the outer ear canal in droplet form”. It is clear from the Saleh et al. document, however, that the entire description and the claims are directed to relatively thick emulsions that are to be applied to the skin in cream form and this assumption is therefore untenable.

Silicone polymers are well known as film forming liquids, as pointed out in the Saleh patent (column 1; lines 63 to 67), but the Saleh et al. document makes use of a large number of these polymers to create the oil phase of an emulsion. Once again this is very different from the simple oil-in-oil formulation of the ear drops of the invention.

It is Applicant's submission that the Saleh et al. document does not describe the present invention in a manner sufficient to anticipate the combination of features set forth in any of independent claims 1, 2 and 7.

Regarding Merat et al.

The Merat et al. application is also directed to a skin protection lotion consisting of a water phase and an oil phase. Notwithstanding that the lotion is described as a liquid, the document does not teach a thin liquid suitable for instillation in the ear and instead proposes a cream-or mousse-type lotion containing waxes and wetting- and emulsifying agents, together with antiseptics, astringents, anti-bacterial agents and emollients to form a protective cream or mousse. This too is very different from the simple oil-in-oil formulation of the ear drops of the invention.

It is Applicant's submission that the Merat et al. document does not describe the combination of features as set forth in any of independent claims 1, 2 and 7.

Regarding Bettie et al.

The same applies to the Bettie et al. document which provides a phase stable emulsion that is intended to bond ionically to the skin. The complex creams and lotions described in the Bettie patent are very different from the simple oil-in-oil formulation of the eardrops of the present invention.

It is Applicant's submission that the Bettie et al. document does not describe the combination of features set forth in any of independent claims 1, 2 and 7.

At least for the reasons explained above, the Applicants respectfully submit that the combination of features set forth in each of independent claims 1, 2 and 7 is not disclosed or made obvious by the prior art of record, including Van Cleave, Saleh et al., Merat et al. and Bettie et al.

Therefore, independent claims 1, 2 and 7 are in condition for allowance.

Dependent Claims

The Examiner will note that dependent claims 6, 8, and 9 have been cancelled, and claims 2 and 5 have been amended to place them in better form, and dependent claims 11-15 are added to set forth additional novel features of the invention.

All dependent claims are in condition for allowance due to their dependency from allowable independent claims, or due to the additional novel features set forth therein.

Accordingly, reconsideration and withdrawal of the rejections under 35 U.S.C. § 102(b) are respectfully requested.

Application No. 10/526,639
Amendment dated September 26, 2008
Reply to Office Action of June 6, 2008

Docket No. 5288-0102PUS1
Art Unit: 1616
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CONCLUSION


All of the stated grounds of rejection have been properly traversed, accommodated, or rendered moot. It is believed that a full and complete response has been made to the outstanding Office Action, and that the present application is in condition for allowance.

If the Examiner believes, for any reason, that personal communication will expedite prosecution of this application, he is invited to telephone Carl T. Thomsen (Reg. No. 50,786) at (703) 208-4030 (direct line).

If necessary, the Commissioner is hereby authorized in this, concurrent, and future replies to charge payment or credit any overpayment to Deposit Account No. 02-2448 for any additional fees required under 37 C.F.R. §§1.16 or 1.17, particularly extension of time fees.

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Respectfully submitted,

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